

APPLICATION FOR UNITED STATES LETTERS PATENT

of

Thomas D. Lyster
Thomas Solosko, Carlton B. Morgan

for

**METHOD AND APPARATUS FOR DEFIBRILLATING PATIENTS
OF ALL AGES**

File No. 10001127 (1727-11)

Certificate of Mailing Under 37 C.F.R. § 1.10

Express Mail Label No. ET450406129US

Date of Deposit: 9-14-01

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Commissioner for Patents, BOX PATENT APPLICATION, Washington, DC 20231.

Stephanie Cox

METHOD AND APPARATUS FOR DEFIBRILLATING PATIENTS OF ALL AGES

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[1] The present invention relates generally to an electrotherapy apparatus and method for delivering a series of shocks to a patient's heart. More particularly, this invention is an Automated External Defibrillator (AED) suitable for defibrillating patients of all ages.

DESCRIPTION OF THE PRIOR ART

[2] Sudden Cardiac Arrest (SCA) is one of the leading causes of death in the industrialized world, and typically results from an arrhythmia condition known as Ventricular Fibrillation (VF), during which a patient's heart muscle exhibits extremely rapid, uncoordinated contractions that render the heart incapable of circulating blood. Statistically, after the first four minutes, the patient's chance of survival decreases by 10% during each subsequent minute they fail to receive treatment.

[3] An effective treatment for VF is electrical defibrillation, in which a defibrillator delivers an electrical pulse or shock to the patient's heart. Because the onset of VF is generally an unpredictable event, the likelihood that a victim will survive rises dramatically if defibrillation equipment is nearby. As a result, medical equipment manufacturers have developed Automated External Defibrillators (AEDs) that minimally trained personnel may employ to perform electrical defibrillation when emergency situations arise. AEDs may be found in non-medical settings such as residences, public buildings, businesses, private vehicles, public transportation vehicles, and airplanes.

[4] To increase a patient's chances of survival, AED operators must perform quickly and accurately in life-threatening situations. Hence, AEDs are typically designed to be simple and intuitive to use. AEDs often automate many of the steps associated with operating external defibrillation equipment, and minimize the number of decisions the operator must make. An AED may provide voice instructions or commands to guide the operator through application of the device.

30 Typically, an AED automatically analyzes a patient's heart rhythm, and determines

when administration of an electrical shock to the patient is appropriate. If a shock is warranted, the AED facilitates delivery of a defibrillation waveform at a particular energy level.

[5] The vast majority of VF situations involve adult patients, as VF tends to be a rare condition in children. Nonetheless, recent evidence suggests that pediatric VF occurs with sufficient frequency to be of concern. AEDs, however, are designed for use on adults. In the past, pediatric application of AEDs had been limited by a lack of data characterizing pediatric Electrocardiogram (ECG) rhythms, which cast doubt upon the effectiveness of ECG detection algorithms that an AED may employ 10 in pediatric situations.

[6] Energy delivery recommendations for children are dependent upon body mass, whereas such recommendations for adults are not. Presently, the recognized treatment for pediatric VF in children less than 8 years of age is manual defibrillation in which delivered energies are proportional to the patient's body weight (1 Joule per kilogram of body weight, increasing to 2 Joules per kilogram if necessary). Incorporating controls to facilitate detailed energy adjustments in accordance with body mass or weight would add extra complexity and cost to AED design. More importantly, providing such controls would undesirably complicate the decisions operators must make during time-critical situations, even when treating 15 adults, thereby providing more opportunity for treatment to fail.

[7] Present defibrillators require differently-sized electrodes for children and adults. Pediatric electrodes are typically 15 to 45 square centimeters each in area, whereas adult electrodes typically exhibit considerably larger areas, for example, 75 to 100 square centimeters each. Unfortunately, adult electrodes are too 25 large to easily place or position upon small children or infants. Conversely, the use of pediatric electrodes upon adult patients may present a total impedance that is too large for effective use. Thus, with the present art, emergency responders must undesirably choose an electrode size appropriate for the victim being treated.

[8] AEDs are typically deployed with electrodes sized for adults rather than 30 children. However, some AEDs include electrodes specifically designed for pediatric use. An AED such as that described in U.S. Patent No. 6,134,468, entitled "Method

and Apparatus for Reducing Defibrillation Energy," which is incorporated herein by reference, includes pediatric size electrodes that are coupled to a connector that attenuates adult shock energies. Such a pediatric electrode and connector configuration facilitates the delivery of a reduced-energy shock to a pediatric patient.

- 5 While an AED could be stocked with one set of electrodes suitable for adults plus another set of electrodes suitable for children, this would undesirably present operators with another series of choices to make during life-threatening VF situations.

[9] What is needed is a defibrillation system capable of treating all human beings with equal ease, regardless of age.

10

SUMMARY OF THE INVENTION

[10] An Automated External Defibrillator (AED) may include an adult/pediatric mode control or switch. Based upon a setting of the adult/pediatric switch, the AED may perform an adult defibrillation sequence or a pediatric defibrillation sequence upon a patient. An adult defibrillation sequence may involve the delivery of one or more defibrillator shocks characterized by an energy appropriate for adults. For example, an adult defibrillation sequence may comprise the delivery of one or more 150 Joule biphasic waveforms to the patient.

[11] A pediatric defibrillation sequence may involve the delivery of one or more defibrillator shocks characterized by an energy appropriate for children who are or seem to be less than eight years of age. For example, a pediatric defibrillation sequence may comprise the delivery of one or more 50 Joule biphasic defibrillator shocks to the patient.

[12] A pediatric defibrillation sequence may alternatively or additionally involve the delivery of one or more escalating-energy waveforms to the patient. Such a pediatric defibrillation sequence may comprise, for example, delivery of a 25 to 50 Joule biphasic waveform to the patient; followed by delivery of a 65 to 75 Joule biphasic waveform, if necessary; followed by delivery of one or more 100 to 115 Joule biphasic waveforms, if necessary.

[13] A universal electrode may comprise an electrode that is smaller than a conventional adult electrode, yet larger than a conventional pediatric electrode. The

universal electrode may include an opening for the purpose of reducing its effective impedance.

Brief Description of the Drawings

[14] FIG. 1 is a schematic block diagram of an Automated External Defibrillator constructed in accordance with the present invention.

[15] FIG. 2A is a top view of a universal electrode according to an embodiment of the invention.

[16] FIG. 2B is a top view showing a universal electrode according to another embodiment of the invention.

[17] FIG. 2C is a graph showing exemplary skin surface current density relative to lateral position beneath the universal electrode of FIG. 2A.

[18] FIG. 2D is a graph showing exemplary skin surface current density relative to lateral position beneath the universal electrode of FIG. 2B.

[19] FIG. 3 is a flowchart of a procedure for defibrillating patients of all ages according to an embodiment of the invention.

[20] FIG. 4 is a flowchart of a procedure for defibrillating patients of all ages according to another embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[21] The following discussion is presented to enable a person skilled in the art to make and use the invention. The general principles described herein may be applied to embodiments and applications other than those detailed below without departing from the spirit and scope of the present invention as defined by the appended claims. The present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein.

AED ARCHITECTURE

[22] FIG. 1 is a block diagram of a universal AED 10 according to an embodiment of the present invention. The AED 10 comprises a power source or battery 12; a power management unit 14; an electrode signal management unit 16;

an electrode interface **18**; a first and a second gate array **20, 22**; a memory **30**; a processing unit **32**; a communication interface or port **34**; an operator interface **40** that includes a power or on/off switch **42**, an adult/pediatric mode control or switch **44**, a status indicator **46**, a contrast control **48**, a display **50**, a speaker **52**, a microphone **54**, a set of Light Emitting Diodes (LEDs) **56**, and a shock button **58**; and a status measurement unit **70**.

[23] The on/off switch **42** may turn the AED **10** on or off in a conventional manner. The status indicator **46** indicates the AED's operational status. The adult/pediatric switch **44** may comprise a switch that specifies an AED operational mode depending upon switch setting. The adult/pediatric switch **44** may facilitate operator specification of whether a patient is an adult or a child less than eight years of age. Depending upon a setting indicated by the adult/pediatric switch **44**, the AED **10** may perform an adult or a pediatric defibrillation sequence, as detailed below. The AED **10** may power-up or initialize in an adult treatment mode, and change to a pediatric treatment mode in response to an AED operator adjusting or setting the adult/pediatric switch **44**. In one embodiment, the adult/pediatric switch **44** comprises a keyed switch, which requires a key turn to place the AED **10** into the pediatric treatment mode.

[24] The electrode interface **18** may be coupled to a plurality of electrodes **100a, 100b** via a connector **110**. The electrodes **100a, 100b** are operable to sense a patient's ECG (not shown) and deliver an electrical waveform or shock to the patient (not shown). Electrode embodiments having universal applicability to both adults and children are described below with reference to FIGS. 2A and 2B.

[25] The electrode signal management unit **16** exchanges signals with the electrodes **100a, 100b** via the electrode interface **18**. During an analysis mode of operation, the electrode signal management unit **16** samples the patient's ECG. During a shock delivery mode of operation, the electrode signal management unit **16** provides a shock to the patient. The electrode signal management unit **16** may provide different types of shock sequences to the patient depending upon a setting indicated by the adult/pediatric switch **44**, as described in detail below. The electrode signal management unit **16** may include impedance compensation circuitry, such as

that described in U.S. Patent No. 6,047,212, entitled "External Defibrillator Capable of Delivering Patient Impedance Compensated Biphasic Waveforms," which is incorporated herein by reference.

5 [26] The first gate array **20** receives ECG samples from the electrode signal management unit **16**, and may transfer this information to the memory **30** and/or the processing unit **32**. The memory **30** may comprise one or more types of Random Access Memory (RAM) and Read-Only Memory (ROM), including Programmable ROM (PROM). The memory **30** stores data, plus program instruction sequences that direct the operation of the processing unit **32** and the gate arrays **20**, **22**. Such
10 program instruction sequences may direct the defibrillation of adult and pediatric patients in the manners described in detail below.

9
8
7
6
5
4
3
2
15 [27] The processing unit **32** may analyze ECG samples, and determine whether the patient is suffering from a shockable heart rhythm. If the patient is suffering from a shockable heart rhythm, the processing unit **32** instructs the electrode signal management unit **16** to enable delivery of an appropriate shock when an operator (not shown) presses the shock button **58**. If the processing unit **32** determines that the patient is not suffering from a shockable heart rhythm, the processing unit **32** may disable the electrode signal management unit's shock delivery capabilities to prevent delivery of a shock to the patient.

20 [28] The power management unit **14** distributes power from the battery **12** to each of the AED's subsystems and/or subcircuits. The second gate array **22** interfaces the power management unit **14**, the on/off switch **42**, the adult/pediatric switch **44**, and the status indicator **46** to the electrode signal management unit **16**, the first gate array **20**, and the processing unit **32**.

25 [29] The display **50** presents visual information to the operator, who may adjust display characteristics via the contrast control **48**. The LEDs **56** may also provide information to the operator, such as whether the processing unit **32** has enabled the electrode signal management unit **16** to deliver a shock to the patient. The speaker **52** may provide audio instructions to the operator, and the
30 microphone **54** may record the operator's voice and/or other audible sounds. The display **50** and/or the speaker **52** may present instructions to the operator relative to

setting the adult/pediatric switch **44**. Such instructions may indicate, for example, that the adult/pediatric switch **44** should be set, moved, or turned to a pediatric mode position in the event that the patient is a child that is or seems, either to the AED operator or the AED **10** itself, to be less than eight years of age.

- 5 [30] The communication port **34** may serve as an interface between the first gate array **20** and a data card **80** or other types of circuitry. In one embodiment, the data card **80** stores the operator's voice and other sounds along with the patient's ECG and a record of AED events for later study. The status measurement unit **70** may monitor the state of various AED subsystems and/or subcircuits, and provides
10 associated status information to the processing unit **32**.

UNIVERSAL ELECTRODES

- 15 [31] One embodiment of the AED system includes the AED **10** of FIG. 1, coupled to a set of universal electrodes having equal applicability to adults and children. Those skilled in the art will recognize that the AED system may include conventional AED electrodes; however, such electrodes are designed for adults and are typically larger than desired for pediatric applications.

- 20 [32] FIG. 2A is a top view of a universal electrode **200** according to an embodiment of the invention. The universal electrode **200** comprises a reduced-size version of a conventional adult electrode, and is larger than a conventional pediatric electrode. The universal electrode **200** includes a conductive adhesive or hydrogel layer **210** upon which a foil layer **220** resides, in a manner readily understood by those skilled in the art. A dashed line **230** in FIG. 2A provides an indication of the size of the universal electrode **200** relative to a standard adult electrode. In one embodiment, the universal electrode **200** has a surface area equal or approximately
25 equal to 50 square centimeters. Those skilled in the art will recognize that various implementations of the universal electrode **200** may exhibit a range of surface areas or sizes.

- 30 [33] As electrode area and/or perimeter decreases, the effective impedance between the electrode and the patient increases. Those skilled in the art will understand that impedance compensation circuitry such as that referenced above

with respect to **FIG. 1** may ensure efficient delivery of a predetermined amount of energy in an effective waveform across the universal electrode **200** for both adult and pediatric patients. Alternatively or additionally, variations in electrode design may significantly reduce effective impedance, as described in detail hereafter.

5 [34] **FIG. 2B** is a top view showing a universal electrode **250** according to another embodiment of the invention. In one embodiment, the universal electrode **250** comprises a conductive adhesive or hydrogel layer **260** and a foil layer **270** having an opening **280** disposed therein. Such an electrode is described in detail in U.S. Patent Application No. 09/*** serial no. ***, entitled "Medical Electrode and Release Liner Configurations Facilitating Packaged Electrode Characterization," filed on September 14, 2001, which is commonly owned and incorporated herein by reference. In a manner analogous to the universal electrode **200** of **FIG. 2A**, the universal electrode **250** of **FIG. 2B** may be smaller than a standard adult electrode.

10 [35] In one embodiment, the opening **280** is generally circular, and has a diameter of approximately 25 to 40 millimeters. Those skilled in the art will recognize that in various embodiments, the universal electrode **250** may have differently sized, differently shaped, and/or multiple openings. Relative to the universal electrode **200** of **FIG. 2A**, the presence of the opening **280** reduces effective impedance by altering the nature of current flow between the universal electrode **250** and a patient's body (not shown).

15 [36] **FIG. 2C** is a graph showing exemplary skin surface current density (J) relative to lateral position (x) beneath the universal electrode **200** of **FIG. 2A**, where the universal electrode **200** is shown in a cross-sectional view. It has been found that the current flows more easily between an electrode and a patient's body near the 20 electrode's edges. As one moves from an interior region **222** toward an outer edge or border **224** of the universal electrode's foil layer **220**, current density increases and peaks.

25 [37] **FIG. 2D** is a graph showing exemplary skin surface current density (J) relative to lateral position (x) beneath the universal electrode **250** of **FIG. 2B**, where 30 the universal electrode **250** is shown in a cross-sectional view. The universal electrode's foil layer **270** includes an outer edge **274** and an inner edge **276**. As one

moves from an interior region **272** toward either of the foil layer's outer or inner edges **274** or **276**, current density increases and peaks.

[38] The current density beneath the universal electrode **200** of FIG. 2A exhibits peaks only in the vicinity of its foil layer's outer edge **224**. However, the 5 current density beneath the universal electrode **250** of FIG. 2B exhibits peaks proximate both its foil layer's outer and inner edges **274** and **276**. This, in turn, advantageously reduces the effective impedance of the universal electrode **250**. Those skilled in the art will recognize that the area under the curve shown in FIG. 2D may be greater than the area under the curve shown in FIG. 2C, indicating a reduced 10 net impedance for the universal electrode **250** of FIG. 2B relative to that for the universal electrode **200** of FIG. 2A.

DEFIBRILLATION METHODS

[39] FIG. 3 is a flowchart of a procedure **300** for defibrillating patients of all ages in accordance with an embodiment of the invention. In one embodiment, the 15 procedure **300** begins in step **302** by determining whether the adult/pediatric switch **44** is set to indicate an adult mode or a pediatric mode. Next, the procedure **300** monitors a patient's ECG in step **304**. In one embodiment, the procedure **300** may employ different ECG monitoring techniques based upon the setting of the adult/pediatric switch **44**.

[40] The procedure **300** next determines whether the patient is suffering from a shockable heart rhythm in step **306**. If not, the procedure **300** may end. If the patient is suffering from a shockable heart rhythm, the procedure **300** initiates or performs a defibrillation sequence based upon the setting of the adult/pediatric switch **44**. If the patient is an adult, the procedure **300** may enable delivery of a first 20 or next shock in an adult defibrillation sequence in step **310**. The adult defibrillation sequence may comprise delivery of one or more shocks to the patient, where such shock waveforms may be characterized by energy levels appropriate for adults. For example, the adult defibrillation sequence may deliver one or more biphasic waveform shocks having an energy of 150 Joules to the patient. An adult 25 defibrillation sequence may alternatively or additionally comprise delivery of one or 30

more escalating energy shocks or waveforms to the patient, where such shocks may be characterized by energies appropriate for adults.

[41] If the patient is a child, where the child is or seems to be less than eight years of age, the procedure may enable delivery of a first or next shock in a pediatric defibrillation sequence in step 320. The pediatric defibrillation sequence may comprise delivery of one or more low-energy waveforms to the patient, such as 50 Joule biphasic waveforms. During one or more of the above steps, the procedure 300 may perform impedance measurement and compensation operations in a conventional manner. Following either of steps 310 or 320, the procedure 300

10 returns to step 304.

[42] FIG. 4 is a flowchart of a procedure 400 for defibrillating patients of all ages in accordance with another embodiment of the invention. The procedure 400 begins in step 402 by determining whether the adult/pediatric switch 44 is set to indicate an adult mode or a pediatric mode. Next, the procedure 400 monitors a patient's ECG in step 404. In one embodiment, the procedure 400 may employ different ECG monitoring techniques based upon the setting of the adult/pediatric switch 44.

[43] The procedure 400 next determines whether the patient is suffering from a shockable heart rhythm in step 406. If not, the procedure 400 may end. If the patient is suffering from a shockable heart rhythm, the procedure 400 initiates or performs a defibrillation sequence based upon the setting of the adult/pediatric switch 44. If the patient is an adult, the procedure 400 may enable delivery of a first or next shock in an adult defibrillation sequence in step 410. The adult defibrillation sequence may comprise delivery of one or more shock waveforms to the patient, where such shock waveforms may be characterized by energy levels appropriate for adults. For example, the adult defibrillation sequence may deliver one or more biphasic shock waveforms having an energy of 150 Joules to the patient. An adult defibrillation sequence may alternatively or additionally comprise delivery of a series of escalating energy shocks or waveforms to the patient, where such shocks may be characterized by energies appropriate for adults.

[44] If the patient is a child, where the child is or seems to be less than eight years of age, the procedure may enable delivery of a first or next shock in an escalating energy pediatric defibrillation sequence in step **420**. An escalating energy pediatric defibrillation sequence may begin with a shock having a low or generally low 5 energy, possibly followed by one or more shocks of higher energy until defibrillation is successful and/or a maximum target shock energy is reached. The escalating energy pediatric defibrillation sequence may comprise delivery of, for example, a 25 to 50 Joule biphasic waveform, followed by a 65 to 75 Joule biphasic waveform (if necessary), followed by one or more 100 to 115 Joule biphasic waveforms (if necessary). Those skilled in the art will recognize that other escalating low-energy 10 shock sequences characterized by different energies and/or a different number of energy increments may be employed in alternate embodiments. Such low-energy shock sequences may be defined in accordance with an energy increment plan. Additionally, if a patient relapses into a shockable heart rhythm condition following a 15 successful defibrillation, the procedure **400** may begin subsequent shock delivery using a most-recently successful shock energy. During one or more of the above steps, the procedure **400** may perform impedance measurement and compensation operations in a conventional manner. Following either of steps **410** or **420**, the procedure **400** returns to step **404**.